K111333

510(k) Summary

Antlia III™ Wound Treatment System

AUG - 8 2011

1.	**Name/Address of Submitter:**	Innovative Therapies, Inc. 12 Meem Ave., Suite C Gaithersburg, MD 20877
2.	**Contact Person:**	Judith Harbour Director, Regulatory and Quality 866.484.6798 x 105
3.	**Date Summary Prepared:**	April 29, 2011
4.	**Name of Device:**	**Antlia III™ Wound Treatment System**
	• **Trade name:**	Negative Pressure Wound Therapy and Wound Dressing kit
	• **Classification Name:**	Powered Suction Pump 21 CFR 878.4780 Class II; Product Code: OMP
5.	**Predicate Device:**	Antlia II™ Suction Pump System 510(k) No.K070904

6. **Description of Device**

The **Antlia III™ Wound Treatment System** is an AC-powered, portable suction device with battery backup that provides localized negative pressure when used with the ITI Dressing to remove fluid and infectious materials from the wound as it may promote wound healing. It is intended for use on patients who would benefit from a suction device, particularly as the device may promote wound healing, including patients who would benefit from vacuum assisted drainage and removal of infectious material, irrigation fluids or other body fluids from wounds.

The Antlia III™ Wound Treatment System consists of the same powered suction pump components and functions the same as the Antlia II Suction Pump device, only housed in a smaller, lighter weight plastic enclosure with a built-in placement holder for the ITI 300cc and 500cc collection canisters, and optional pressure settings of -50mmHg, -75mmHg, -100mmHg, - 125mmHg, and -150mmHg.

7. Indication for Use

The Antlia III™ Wound Treatment System is indicated for the application of suction (negative pressure) to wounds as it may promote wound healing and for the removal of fluid, including wound exudates, irrigation fluids, body fluids and infectious materials.

8. Technological Characteristics of the device

The Antlia III™ Wound Treatment System Unit is smaller in size and weighs less compared to the predicate Antlia II powered suction pump, yet has the same technological characteristics and functions as the Antlia II™ Suction Pump System.

9. Summary of Non-clinical tests conducted for Substantial Equivalence

Testing in accordance with IEC 60601-1 was conducted for electrical safety.

Testing in accordance with IEC 60601-1-2 was conducted for electromagnetic compatibility.

Verification and Validation activities, as required by the risk analyses for the Antlia III device modifications, were performed and demonstrated that the predetermined acceptance criteria were met.

10. Conclusion

Testing demonstrates that the Antlia III™ Wound Treatment System is substantially equivalent to the predicate device in terms of safety and effectiveness and has the same indications and intended use and same technological features of Antlia II.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Innovative Therapies, Inc.
% Ms. Judith Harbour
Director, Quality and Regulatory Affairs
12 Meem Avenue, Suite C
Gaithersburg, Maryland 20877

AUG - 8 2011

Re: K111333
Trade/Device Name: Antila III™ Wound Treatment System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: II
Product Code: OMP
Dated: July 14, 2011
Received: July 15, 2011

Dear Ms. Harbour:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111333

Device Name: Antlia III™ Wound Treatment System

Indications for Use:

The Antlia III™ Wound Treatment System is indicated for the application of suction (negative pressure) to wounds as it may promote wound healing and for the removal of fluids, including wound exudates, irrigation fluids, body fluids and infectious materials.

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K111333